

**MAY 14 2014**

**SECTION 5 510(k) SUMMARY**

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**1. Submitter**

Boston Scientific Corporation  
100 Boston Scientific Way  
Marlborough, MA 01752

**Contact:** Elena Nieves  
Principal, Regulatory Affairs Specialist  
Telephone: 508-683-4430  
Fax: 508-683-5939

Date Prepared: November 26, 2013

**2. Device**

Trade Name:	Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers
Classification Name:	Biliary Catheters and Accessories
Product Code:	FGE - Biliary Catheter and accessory
Device Class and panel:	Class II, Gastroenterology/Urology
Classification Regulation:	CFR 876.5010

**3. Predicate Devices**

Trade Name:	Zimmon Endoscopic Pancreatic Stent
Trade Name:	Geenen Pancreatic Stent
Manufacturer and Clearance Number:	Wilson-Cook, K900923
Classification Name:	Biliary Catheters and Accessories
Product Code:	FGE - Biliary Catheter and accessory
Device Class and panel:	Class II, Gastroenterology/Urology
Classification Regulation:	CFR 876.5010
Trade Name:	Advanix™ Biliary Stent with NaviFlex™ RX Delivery System
Manufacturer and Clearance Number:	Boston Scientific Corporation, K101314
Classification Name:	Biliary Catheters and Accessories
Product Code:	FGE - Biliary Catheter and accessory
Device Class and panel:	Class II, Gastroenterology/Urology
Classification Regulation:	CFR 876.5010

**4. Device Description**

The Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers product consists of pancreatic stents and delivery systems or stent pushers.

The pancreatic stents are provided in straight or single pigtail shape. The straight shape stents have trailing barbs and/or leading barbs depending on application, a rounded or tapered leading end tip to facilitate access through the papilla, and a rounded trailing end to abut the push catheter portion of the delivery system or stent pusher. The single pigtail stent may or may not have leading end barbs depending on application. Some stents have lateral drainage holes in the pigtails, a tapered or rounded leading end tip, and a rounded trailing end. All stents have either an endoscopic marker, fluoroscopic marker, or both on the trailing or leading end of the stent to assist with depth of placement in the pancreatic duct. The location and presence of an endoscopic or fluoroscopic marker is dependent on the length and diameter size of the stent. Some codes have side port holes in the body of the stent.

#### **5. Indication for Use:**

The Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers is intended for delivery of the stent to the pancreatic duct (PD):

- Used to drain pancreatic ducts

#### **6. Technological Characteristics:**

The Advanix Pancreatic Stent is designed for pancreatic duct (PD) drainage. The stent is constructed of a radiopaque (RO) polymer. The leading end has a tapered or rounded tip and the trailing end of the stent has an endoscopically visible marker to aid in placement. Stent sizes 4F and 5F contain a RO marker while 3F stents do not. The stent is available in two different shapes: straight stent and single pigtail. 3F and 4F stents have no-leading barb; 5F stents are available with and without a leading barb. Stent sizes 7F and 10F contain an RO marker except for the 3cm length stents. The 7F stent is available in two different shapes: straight stent and single pigtail. The 10F stent is only available in the straight stent shape.

The pusher is constructed of RO polymer. The trailing end of the pusher has a white indicator to indicate the non-working end. There are 2 pusher options: RX and longwire. The RX pusher has a guidewire exit marker on the leading end to indicate the guidewire exit location. The wire for the longwire pusher exits at the trailing end of the pusher.

The delivery system consists of a guide catheter connected to a pull-wire, and a push catheter connected to a locking mechanism. The locking mechanism is designed to keep the guide catheter in the position desired while being delivered to the deployment site. The stent can be deployed by disengaging the locking mechanism and retracting the guide catheter.

The delivery system, stent pushers and stent for this product have the following technological characteristics:

- Range of delivery systems and pushers tailored to the stents
- Range of stents that are deliverable and removable through the endoscope
- Stents with a pigtail, and trailing and/or leading barbs
- Radiopaque stent, pusher and delivery system designed to be easily identifiable under fluoroscopy.

When compared with the predicate devices [Boston Scientific Advanix Biliary Stent with NaviFlex RX Delivery System (K101314), Wilson-Cook Zimmon Pancreatic Stent (K900923), and Wilson-Cook Geenen Pancreatic Stent (K900923)] the proposed Advanix Pancreatic Stent and NaviFlex RX Pancreatic Delivery System and Pushers has the same the technological characteristics as follows: identical indication statement; offered in the same stent lengths that range from 2cm -18cm; offered in the same stent shape configurations (straight and single pigtail; leading and no-leading barb); offered in the same stent outer diameter that range from 3F to 10F; offered in the same Pusher outer diameter (OD) that range from 3F to 5F; offered in the delivery system OD that range from 7F to 10F; and offered in the same delivery system working length of 202.5cm. The proposed devices technological characteristics that are similar in comparison to the predicate device are the stent and delivery system materials, and pusher working length.

#### **7. Performance Data:**

The proposed Boston Scientific Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers were evaluated in accordance with EN ISO 10993-1:2009- Evaluation and Testing within a risk management system. The following tests were performed on the stent: Cytotoxicity, Irritation, Sensitization, Acute Systemic Toxicity, Subchronic Toxicity, Genotoxicity, Implant, USP Physicochemical, and Latex.

The delivery system and pushers were evaluated in accordance with EN ISO 10993-1:2009. The following tests were performed on the delivery system and pushers: Cytotoxicity, Sensitization, Irritation, USP Physicochemical and Latex.

The following tests were conducted on the Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers: Drainage Lumen ID, Stent Length, Stent Outer Diameter, Pigtail Stent Shape, Pigtail Stent Diameter, No-Leading Barb Stent Stiffness, Leading Barb Stent Stiffness, Stent Tensile, Pusher Working Length, Delivery System Working Length, Pusher OD, Delivery System Push Catheter OD, Pusher Deployment Force, Delivery System Deployment Force, Pusher Trackability Force, and Delivery System Trackability Force.

#### **8. Conclusion:**

Boston Scientific Corporation has demonstrated that the proposed Boston Scientific Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers is substantially equivalent to the currently marketed Boston Scientific Corporation Advanix™ Biliary Stent with NaviFlex™ RX Delivery System (K101314), Wilson-Cook Zimmon Endoscopic Pancreatic Stent (K900923) and Wilson-Cook Geenen Pancreatic Stent (K900923).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

May 14, 2014

Boston Scientific Corporation  
Elena Nieves  
Principle, Regulatory Affairs Specialist  
100 Boston Scientific Way  
Marlborough, MA 01752

Re: K133700  
Trade/Device Name: Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX)  
Pancreatic Delivery System and Pushers  
Regulation Number: 21 CFR§ 876.5010  
Regulation Name: Biliary catheter and accessories  
Regulatory Class: II  
Product Code: FGE  
Dated: April 17, 2014  
Received: April 21, 2014

Dear Elena Nieves,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Benjamin R. Fisher -S**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**SECTION 4 INDICATIONS  
FOR USE STATEMENT**

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Indications for Use:

510(k) Number (if known): K133700

Device Name: Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic  
Delivery System and Pushers

Indications for Use:

The Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers are intended for delivery of the stent to the pancreatic duct (PD):

- Used to drain pancreatic ducts

Prescription Use X  
(Part 21 CFR 801 Part D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S  
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